

I claim:

1. A composition for sealing a vascular puncture site comprising

a first component including an electrophilic polymer material having a functionality of at least three,

5 a second component including a nucleophilic material that, when mixed with the first component within a reaction pH range of between 7 to 9, cross-links with the first component to form a non-liquid, three-dimensional barrier, and

10 a buffer material mixed with the second component and having a pH within the reaction pH range.

2. A composition according to claim 1

wherein the first component includes poly(ethylene glycol), poly(ethylene oxide), poly(vinyl alcohol), poly(vinylpyrrolidinone), poly(ethyloxazoline), 5 and poly(ethylene glycol)-co-poly(propylene glycol) block copolymers.

3. A composition according to claim 1

wherein the first component comprises poly(ethylene glycol) having a molecular weight between 9000 and 12,000.

4. A composition according to claim 4

wherein the molecular weight is 10,500 ± 1500.

5. A composition according to claim 1

wherein the first component includes a degradation control region selected to achieve a desired degradation period, during which the non-liquid, three-dimensional barrier degrades over time back to a liquid form,

5 6. A material according to claim 1

wherein the first component comprises a compound of the formula PEG-(DCR-CG)_n, where PEG is poly(ethylene glycol), DCR is a degradation control region, CG is a cross-linking group, and n is equal to or greater than three.

7. A composition according to claim 6
wherein the second component and buffer material,
when mixed, have a pH of between 8.3 and 8.5 prior to mixing
with the first component.

8. A material according to claim 6
wherein the cross-linking group is selected
to react with at least one thiol.

9. A material according to claim 8
wherein the cross-linking group is selected from
a group consisting essentially of vinyl sulfone, N-ethyl
maleimide, iodoacetamide, and orthopyridyl disulfide.

10. A material according to claim 6
wherein the cross-linking group is selected
to react with at least one amine.

11. A material according to claim 10
wherein the cross-linking group is selected from
a group consisting essentially of aldehydes.

12. A material according to claim 6
wherein the cross-linking group is selected from
a group consisting essentially of active esters, epoxides,
oxycarbonylimidazole, nitrophenyl carbonates, tresylate,
mesylate, tosylate, and isocyanate.

13. A material according to claim 6
wherein the cross-linking group includes an ester
of N-hydroxysuccinimide.

14. A composition according to claim 1
wherein the first component comprises a multi-
armed polymer structure.

15. A composition according to claim 1
wherein the second component comprises a
hydrophilic protein.

16. A composition according to claim 15
wherein the hydrophilic protein is selected from
a group consisting essentially of serum, serum fractions,
and solutions of albumin, gelatin, antibodies, fibrinogen,

5 and serum proteins.

17. A composition according to claim 15
wherein the hydrophilic protein comprises at least one water soluble derivative of a hydrophobic protein.

18. A composition according to claim 17
wherein the water soluble derivative of a hydrophobic protein is selected from a group consisting essentially of comprising solutions of collagen, elastin,
5 chitosan, and hyaluronic acid.

19. A composition according to claim 17
wherein the hydrophilic protein comprises at least one hybrid protein.

20. A composition according to claim 15
wherein the hydrophilic protein comprises at least one synthetic amino acid sequence.

21. A composition according to claim 15
wherein the hydrophilic protein comprises recombinant or natural human serum albumin.

22. A material according to claim 15
wherein the hydrophilic protein comprises human serum albumin at a concentration of about 25% or less.

23. A composition according to claim 1
wherein the buffer material includes tris-hydroxymethylaminomethane.

24. A composition according to claim 23
wherein the buffer material includes sodium carbonate anhydrous.

25. A composition for sealing a vascular puncture site comprising

5 a first component including poly(ethylene glycol) having a molecular weight between 9000 and 12,000 and having a functionality of at least three,

a second component including human albumin at a concentration not greater than 25% that, when mixed with the first component within a reaction pH range of between 7 to

9, cross-links with the first component to form a non-
10 liquid, three-dimensional barrier, and

a buffer material including tris-hydroxymethylaminomethane mixed with the second component and having a pH within the reaction pH range.

26. A composition according to claim 25
wherein the composition comprises a buffered albumin formulation comprising about .217 to 0.290 grams of tris-hydroxymethylaminomethane per 20 ml of human albumin,
5 mixed with a poly(ethylene glycol) formulation comprising poly(ethylene glycol) suspended in water, the mixture of the buffer albumin formulation and the poly(ethylene glycol) formulation having a weight to weight ratio between the poly(ethylene glycol) and the human albumin that lays within
10 a range of about 1 to about 0.6 to 1.8.

27. A composition according to claim 26
wherein the weight to weight ratio is about 1 to
1.

28. A composition according to claim 25
wherein the buffer material includes sodium carbonate anhydrous.

29. A composition according to claim 25
wherein the composition comprises a buffered albumin formulation comprising about .217 to 0.290 grams of tris-hydroxymethylaminomethane and about 0.075 to 0.138
5 grams of sodium carbonate anhydrous per 20 ml of human albumin, mixed with a poly(ethylene glycol) formulation comprising poly(ethylene glycol) suspended in water, the mixture of the buffer albumin formulation and the poly(ethylene glycol) formulation having a weight to weight
10 ratio between the poly(ethylene glycol) and the human albumin that lays within a range of about 1 to about 0.6 to 1.8.

30. A composition according to claim 29
wherein the weight to weight ratio is about 1 to

1.

31. A composition according to claim 25 wherein the first component has a molecular weight of $10,500 \pm 1500$.

32. A composition according to claim 25 wherein the second component, when mixed with the buffer material, has a pH of between 8.3 and 8.5 prior to mixing with the first component.

33. A system for forming a biocompatible material comprising

a first component including electrophilic polymer material having a functionality of at least three,

5 a second component including a nucleophilic material that, when mixed with the first component within a reaction pH range of between 7 to 9, cross-links with the first component to form a non-liquid, three-dimensional barrier,

10 a buffer material mixed with the second component and having a pH within the reaction pH range, and

instructions for forming a mixture of the first component, second component, and buffer material and for applying the mixture to seal a vascular puncture site.

34. A system according to claim 33 wherein the first component comprises poly(ethylene glycol) having a molecular weight between 9000 and 12,000.

35. A system according to claim 34 wherein the poly(ethylene glycol) has a molecular weight of $10,500 \pm 1500$.

36. A system according to claim 34 wherein the second component comprises human serum albumin at a concentration of about 25% or less.

37. A system according to claim 36 wherein the buffer material includes tris-hydroxymethylaminomethane.

38. A system according to claim 37
wherein the buffer material includes sodium carbonate anhydrous.

39. A system according to claim 38
wherein the second component, when mixed with the buffer material, has a pH of between 8.3 and 8.5 prior to mixing with the first component.

40. A method for sealing a vascular puncture site comprising the steps of

mixing a first component, a second component, and a buffer material, the first component including an electrophilic polymer material having a functionality of at least three, the second component including a nucleophilic material that, when mixed with the first component within a reaction pH range of between 7 to 9, cross-links with the first component to form a non-liquid, three-dimensional barrier, and the buffer material having a pH within the reaction pH range, and

applying the mixture to seal a vascular puncture site.

41. A method according to claim 40
wherein the first component comprises poly(ethylene glycol) having a molecular weight between 9000 and 12,000.

42. A method according to claim 41
wherein the poly(ethylene glycol) has a molecular weight of $10,500 \pm 1500$.

43. A method according to claim 41
wherein the second component comprises human serum albumin at a concentration of about 25% or less.

44. A method according to claim 43
wherein the buffer material includes tris-hydroxymethylaminomethane.

45. A method according to claim 44
wherein the buffer material includes sodium

carbonate anhydrous.

46. A method according to claim 45
wherein the second component, when mixed with the
buffer material, has a pH of between 8.3 and 8.5 prior to
mixing with the first component.

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